

Pt. 1404

opinion of the agency, is failing to comply with Circular.

21. Regulations. Each Federal agency shall include the provisions of this Circular in its regulations implementing the Single Audit Act.

22. Effective date. This Circular is effective upon publication and shall apply to fiscal years of State and local governments that begin after December 31, 1984. Earlier implementation is encouraged. However, until it is implemented, the audit provisions of Attachment P to Circular A-102 shall continue to be observed.

23. Inquiries. All questions or inquiries should be addressed to Financial Management Division, Office of Management and Budget, telephone number (202) 395-3993.

24. Sunset review date. This Circular shall have an independent policy review to ascertain its effectiveness three years from the date of issuance.

David A. Stockman,
Director.

CIRCULAR A-128 ATTACHMENT

DEFINITION OF MAJOR PROGRAM AS PROVIDED IN PUB. L. 98-502

“Major Federal Assistance Program,” for State and local governments having Federal assistance expenditures between \$100,000 and \$100,000,000. means any program for which Federal expenditures during the applicable year exceed the larger of \$300,000, or 3 percent of such total expenditures.

Where total expenditures of Federal assistance exceed \$100,000,000, the following criteria apply:

Total expenditures of Federal financial assistance for all programs		Major Federal assistance program means any program that exceeds
More than	But less than	
\$100 million	1 billion	\$3 million
1 billion	2 billion	4 million
2 billion	3 billion	7 million
3 billion	4 billion	10 million
4 billion	5 billion	13 million
5 billion	6 billion	16 million
6 billion	7 billion	19 million
Over 7 billion		20 million

[57 FR 55092, Nov. 24, 1992; 58 FR 26185, Apr. 30, 1993]

PART 1404—GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT)

Sec.

1404.25 How is this part organized?

1404.50 How is this part written?

1404.75 Do terms in this part have special meanings?

21 CFR Ch. III (4-1-11 Edition)

Subpart A—General

1404.100 What does this part do?

1404.105 Does this part apply to me?

1404.110 What is the purpose of the non-procurement debarment and suspension system?

1404.115 How does an exclusion restrict a person's involvement in covered transactions?

1404.120 May we grant an exception to let an excluded person participate in a covered transaction?

1404.125 Does an exclusion under the non-procurement system affect a person's eligibility for Federal procurement contracts?

1404.130 Does exclusion under the Federal procurement system affect a person's eligibility to participate in nonprocurement transactions?

1404.135 May the Office of National Drug Control Policy exclude a person who is not currently participating in a non-procurement transaction?

1404.140 How do I know if a person is excluded?

1404.145 Does this part address persons who are disqualified, as well as those who are excluded from nonprocurement transactions?

Subpart B—Covered Transactions

1404.200 What is a covered transaction?

1404.205 Why is it important to know if a particular transaction is a covered transaction?

1404.210 Which nonprocurement transactions are covered transactions?

1404.215 Which nonprocurement transactions are not covered transactions?

1404.220 Are any procurement contracts included as covered transactions?

1404.225 How do I know if a transaction in which I may participate is a covered transaction?

Subpart C—Responsibilities of Participants Regarding Transactions

DOING BUSINESS WITH OTHER PERSONS

1404.300 What must I do before I enter into a covered transaction with another person at the next lower tier?

1404.305 May I enter into a covered transaction with an excluded or disqualified person?

1404.310 What must I do if a Federal agency excludes a person with whom I am already doing business in a covered transaction?

1404.315 May I use the services of an excluded person as a principal under a covered transaction?

Office of National Drug Control Policy

Pt. 1404

1404.320 Must I verify that principals of my covered transactions are eligible to participate?

1404.325 What happens if I do business with an excluded person in a covered transaction?

1404.330 What requirements must I pass down to persons at lower tiers with whom I intend to do business?

DISCLOSING INFORMATION—PRIMARY TIER PARTICIPANTS

1404.335 What information must I provide before entering into a covered transaction with the Office of National Drug Control Policy?

1404.340 If I disclose unfavorable information required under §1404.335, will I be prevented from participating in the transaction?

1404.345 What happens if I fail to disclose the information required under §1404.335?

1404.350 What must I do if I learn of the information required under §1404.335 after entering into a covered transaction with the Office of National Drug Control Policy?

DISCLOSING INFORMATION—LOWER TIER PARTICIPANTS

1404.355 What information must I provide to a higher tier participant before entering into a covered transaction with that participant?

1404.360 What happens if I fail to disclose the information required under §1404.355?

1404.365 What must I do if I learn of information required under §1404.355 after entering into a covered transaction with a higher tier participant?

Subpart D—Responsibilities of Office of National Drug Control Policy Officials Regarding Transactions

1404.400 May I enter into a transaction with an excluded or disqualified person?

1404.405 May I enter into a covered transaction with a participant if a principal of the transaction is excluded?

1404.410 May I approve a participant's use of the services of an excluded person?

1404.415 What must I do if a Federal agency excludes the participant or a principal after I enter into a covered transaction?

1404.420 May I approve a transaction with an excluded or disqualified person at a lower tier?

1404.425 When do I check to see if a person is excluded or disqualified?

1404.430 How do I check to see if a person is excluded or disqualified?

1404.435 What must I require of a primary tier participant?

1404.440 What method do I use to communicate those requirements to participants?

1404.445 What action may I take if a primary tier participant knowingly does business with an excluded or disqualified person?

1404.450 What action may I take if a primary tier participant fails to disclose the information required under §1404.335?

1404.455 What may I do if a lower tier participant fails to disclose the information required under §1404.355 to the next higher tier?

Subpart E—Excluded Parties List System

1404.500 What is the purpose of the Excluded Parties List System (EPLS)?

1404.505 Who uses the EPLS?

1404.510 Who maintains the EPLS?

1404.515 What specific information is in the EPLS?

1404.520 Who places the information into the EPLS?

1404.525 Whom do I ask if I have questions about a person in the EPLS?

1404.530 Where can I find the EPLS?

Subpart F—General Principles Relating to Suspension and Debarment Actions

1404.600 How do suspension and debarment actions start?

1404.605 How does suspension differ from debarment?

1404.610 What procedures does the Office of National Drug Control Policy use in suspension and debarment actions?

1404.615 How does the Office of National Drug Control Policy notify a person of a suspension and debarment action?

1404.620 Do Federal agencies coordinate suspension and debarment actions?

1404.625 What is the scope of a suspension or debarment action?

1404.630 May the Office of National Drug Control Policy impute the conduct of one person to another?

1404.635 May the Office of National Drug Control Policy settle a debarment or suspension action?

1404.640 May a settlement include a voluntary exclusion?

1404.645 Do other Federal agencies know if the Office of National Drug Control Policy agrees to a voluntary exclusion?

Subpart G—Suspension

1404.700 When may the suspending official issue a suspension?

1404.705 What does the suspending official consider in issuing a suspension?

1404.710 When does a suspension take effect?

1404.715 What notice does the suspending official give me if I am suspended?

§ 1404.25

- 1404.720 How may I contest a suspension?
 1404.725 How much time do I have to contest a suspension?
 1404.730 What information must I provide to the suspending official if I contest a suspension?
 1404.735 Under what conditions do I get an additional opportunity to challenge the facts on which the suspension is based?
 1404.740 Are suspension proceedings formal?
 1404.745 How is fact-finding conducted?
 1404.750 What does the suspending official consider in deciding whether to continue or terminate my suspension?
 1404.755 When will I know whether the suspension is continued or terminated?
 1404.760 How long may my suspension last?

Subpart H—Debarment

- 1404.800 What are the causes for debarment?
 1404.805 What notice does the debarring official give me if I am proposed for debarment?
 1404.810 When does a debarment take effect?
 1404.815 How may I contest a proposed debarment?
 1404.820 How much time do I have to contest a proposed debarment?
 1404.825 What information must I provide to the debarring official if I contest a proposed debarment?
 1404.830 Under what conditions do I get an additional opportunity to challenge the facts on which the proposed debarment is based?
 1404.835 Are debarment proceedings formal?
 1404.840 How is fact-finding conducted?
 1404.845 What does the debarring official consider in deciding whether to debar me?
 1404.850 What is the standard of proof in a debarment action?
 1404.855 Who has the burden of proof in a debarment action?
 1404.860 What factors may influence the debarring official's decision?
 1404.865 How long may my debarment last?
 1404.870 When do I know if the debarring official debars me?
 1404.875 May I ask the debarring official to reconsider a decision to debar me?
 1404.880 What factors may influence the debarring official during reconsideration?

21 CFR Ch. III (4–1–11 Edition)

- 1404.885 May the debarring official extend a debarment?

Subpart I—Definitions

- 1404.900 Adequate evidence.
 1404.905 Affiliate.
 1404.910 Agency.
 1404.915 Agent or representative.
 1404.920 Civil judgment.
 1404.925 Conviction.
 1404.930 Debarment.
 1404.935 Debarring official.
 1404.940 Disqualified.
 1404.945 Excluded or exclusion.
 1404.950 Excluded Parties List System.
 1404.955 Indictment.
 1404.960 Ineligible or ineligibility.
 1404.965 Legal proceedings.
 1404.970 Nonprocurement transaction.
 1404.975 Notice.
 1404.980 Participant.
 1404.985 Person.
 1404.990 Preponderance of the evidence.
 1404.995 Principal.
 1404.1000 Respondent.
 1404.1005 State.
 1404.1010 Suspending official.
 1404.1015 Suspension.
 1404.1020 Voluntary exclusion or voluntarily excluded.

Subpart J [Reserved]

APPENDIX TO PART 1404—COVERED TRANSACTIONS

AUTHORITY: E.O. 12549 3 CFR 1986 Comp., p. 189; E.O. 12689 3 CFR 1989 Comp., p. 235; sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note); 21 U.S.C. 1701.

SOURCE: 68 FR 66544, 66580, 66581, Nov. 26, 2003, unless otherwise noted.

§ 1404.25 How is this part organized?

(a) This part is subdivided into ten subparts. Each subpart contains information related to a broad topic or specific audience with special responsibilities, as shown in the following table:

In subpart . . .	You will find provisions related to . . .
A	general information about this rule.
B	the types of Office of National Drug Control Policy transactions that are covered by the Government-wide nonprocurement suspension and debarment system.
C	the responsibilities of persons who participate in covered transactions.
D	the responsibilities of Office of National Drug Control Policy officials who are authorized to enter into covered transactions.
E	the responsibilities of Federal agencies for the <i>Excluded Parties List System</i> (Disseminated by the General Services Administration).
F	the general principles governing suspension, debarment, voluntary exclusion and settlement.
G	suspension actions.
H	debarment actions.
I	definitions of terms used in this part.

In subpart . . .	You will find provisions related to . . .
J	[Reserved]

(b) The following table shows which subparts may be of special interest to you, depending on who you are:

If you are . . .	See subpart(s) . . .
(1) a participant or principal in a non-procurement transaction.	A, B, C, and I.
(2) a respondent in a suspension action	A, B, F, G and I.
(3) a respondent in a debarment action	A, B, F, H and I.
(4) a suspending official	A, B, D, E, F, G and I.
(5) a debarring official	A, B, D, E, F, H and I.
(6) a (n) Office of National Drug Control Policy official authorized to enter into a covered transaction.	A, B, D, E and I.
(7) Reserved	J.

§ 1404.50 How is this part written?

(a) This part uses a “plain language” format to make it easier for the general public and business community to use. The section headings and text, often in the form of questions and answers, must be read together.

(b) Pronouns used within this part, such as “I” and “you,” change from subpart to subpart depending on the audience being addressed. The pronoun “we” always is the Office of National Drug Control Policy.

(c) The “Covered Transactions” diagram in the appendix to this part shows the levels or “tiers” at which the Office of National Drug Control Policy enforces an exclusion under this part.

§ 1404.75 Do terms in this part have special meanings?

This part uses terms throughout the text that have special meaning. Those terms are defined in Subpart I of this part. For example, three important terms are—

(a) *Exclusion or excluded*, which refers only to discretionary actions taken by a suspending or debarring official under this part or the Federal Acquisition Regulation (48 CFR part 9, subpart 9.4);

(b) *Disqualification or disqualified*, which refers to prohibitions under specific statutes, executive orders (other than Executive Order 12549 and Executive Order 12689), or other authorities.

Disqualifications frequently are not subject to the discretion of an agency official, may have a different scope than exclusions, or have special conditions that apply to the disqualification; and

(c) *Ineligibility or ineligible*, which generally refers to a person who is either excluded or disqualified.

Subpart A—General

§ 1404.100 What does this part do?

This part adopts a governmentwide system of debarment and suspension for Office of National Drug Control Policy nonprocurement activities. It also provides for reciprocal exclusion of persons who have been excluded under the Federal Acquisition Regulation, and provides for the consolidated listing of all persons who are excluded, or disqualified by statute, executive order, or other legal authority. This part satisfies the requirements in section 3 of Executive Order 12549, “Debarment and Suspension” (3 CFR 1986 Comp., p. 189), Executive Order 12689, “Debarment and Suspension” (3 CFR 1989 Comp., p. 235) and 31 U.S.C. 6101 note (Section 2455, Public Law 103-355, 108 Stat. 3327).

§ 1404.105 Does this part apply to me?

Portions of this part (see table at § 1404.25(b)) apply to you if you are a(n)—

(a) Person who has been, is, or may reasonably be expected to be, a participant or principal in a covered transaction;

(b) Respondent (a person against whom the Office of National Drug Control Policy has initiated a debarment or suspension action);

(c) Office of National Drug Control Policy debarring or suspending official; or

(d) Office of National Drug Control Policy official who is authorized to enter into covered transactions with non-Federal parties.

§ 1404.110 What is the purpose of the nonprocurement debarment and suspension system?

(a) To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible persons.

(b) A Federal agency uses the nonprocurement debarment and suspension system to exclude from Federal programs persons who are not presently responsible.

(c) An exclusion is a serious action that a Federal agency may take only to protect the public interest. A Federal agency may not exclude a person or commodity for the purposes of punishment.

§ 1404.115 How does an exclusion restrict a person's involvement in covered transactions?

With the exceptions stated in §§ 1404.120, 1404.315, and 1404.420, a person who is excluded by the Office of National Drug Control Policy or any other Federal agency may not:

(a) Be a participant in a(n) Office of National Drug Control Policy transaction that is a covered transaction under subpart B of this part;

(b) Be a participant in a transaction of any other Federal agency that is a covered transaction under that agency's regulation for debarment and suspension; or

(c) Act as a principal of a person participating in one of those covered transactions.

§ 1404.120 May we grant an exception to let an excluded person participate in a covered transaction?

(a) The Director of National Drug Control Policy may grant an exception permitting an excluded person to participate in a particular covered transaction. If the Director of National Drug Control Policy grants an exception, the exception must be in writing and state the reason(s) for deviating from the governmentwide policy in Executive Order 12549.

(b) An exception granted by one agency for an excluded person does not extend to the covered transactions of another agency.

§ 1404.125 Does an exclusion under the nonprocurement system affect a person's eligibility for Federal procurement contracts?

If any Federal agency excludes a person under its nonprocurement common rule on or after August 25, 1995, the excluded person is also ineligible to participate in Federal procurement transactions under the FAR. Therefore, an exclusion under this part has reciprocal effect in Federal procurement transactions.

§ 1404.130 Does exclusion under the Federal procurement system affect a person's eligibility to participate in nonprocurement transactions?

If any Federal agency excludes a person under the FAR on or after August 25, 1995, the excluded person is also ineligible to participate in nonprocurement covered transactions under this part. Therefore, an exclusion under the FAR has reciprocal effect in Federal nonprocurement transactions.

§ 1404.135 May the Office of National Drug Control Policy exclude a person who is not currently participating in a nonprocurement transaction?

Given a cause that justifies an exclusion under this part, we may exclude any person who has been involved, is currently involved, or may reasonably be expected to be involved in a covered transaction.

§ 1404.140 How do I know if a person is excluded?

Check the *Excluded Parties List System (EPLS)* to determine whether a person is excluded. The General Services Administration (GSA) maintains the *EPLS* and makes it available, as detailed in subpart E of this part. When a Federal agency takes an action to exclude a person under the nonprocurement or procurement debarment and suspension system, the agency enters the information about the excluded person into the *EPLS*.

§ 1404.145 Does this part address persons who are disqualified, as well as those who are excluded from nonprocurement transactions?

Except if provided for in Subpart J of this part, this part—

Office of National Drug Control Policy

§ 1404.215

(a) Addresses disqualified persons only to—

(1) Provide for their inclusion in the *EPLS*; and

(2) State responsibilities of Federal agencies and participants to check for disqualified persons before entering into covered transactions.

(b) Does not specify the—

(1) Office of National Drug Control Policy transactions for which a disqualified person is ineligible. Those transactions vary on a case-by-case basis, because they depend on the language of the specific statute, Executive order, or regulation that caused the disqualification;

(2) Entities to which the disqualification applies; or

(3) Process that the agency uses to disqualify a person. Unlike exclusion, disqualification is frequently not a discretionary action that a Federal agency takes.

Subpart B—Covered Transactions

§ 1404.200 What is a covered transaction?

A covered transaction is a nonprocurement or procurement transaction that is subject to the prohibitions of this part. It may be a transaction at—

(a) The primary tier, between a Federal agency and a person (see appendix to this part); or

(b) A lower tier, between a participant in a covered transaction and another person.

§ 1404.205 Why is it important if a particular transaction is a covered transaction?

The importance of a covered transaction depends upon who you are.

(a) As a participant in the transaction, you have the responsibilities laid out in Subpart C of this part. Those include responsibilities to the person or Federal agency at the next higher tier from whom you received the transaction, if any. They also include responsibilities if you subsequently enter into other covered transactions with persons at the next lower tier.

(b) As a Federal official who enters into a primary tier transaction, you

have the responsibilities laid out in subpart D of this part.

(c) As an excluded person, you may not be a participant or principal in the transaction unless—

(1) The person who entered into the transaction with you allows you to continue your involvement in a transaction that predates your exclusion, as permitted under § 1404.310 or § 1404.415; or

(2) A(n) Office of National Drug Control Policy official obtains an exception from the Director of National Drug Control Policy to allow you to be involved in the transaction, as permitted under § 1404.120.

§ 1404.210 Which nonprocurement transactions are covered transactions?

All nonprocurement transactions, as defined in § 1404.970, are covered transactions unless listed in § 1404.215. (See appendix to this part.)

§ 1404.215 Which nonprocurement transactions are not covered transactions?

The following types of nonprocurement transactions are not covered transactions:

(a) A direct award to—

(1) A foreign government or foreign governmental entity;

(2) A public international organization;

(3) An entity owned (in whole or in part) or controlled by a foreign government; or

(4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.

(b) A benefit to an individual as a personal entitlement without regard to the individual's present responsibility (but benefits received in an individual's business capacity are not excepted). For example, if a person receives social security benefits under the Supplemental Security Income provisions of the Social Security Act, 42 U.S.C. 1301 et seq., those benefits are not covered transactions and, therefore, are not affected if the person is excluded.

(c) Federal employment.

(d) A transaction that the Office of National Drug Control Policy needs to

§ 1404.220

respond to a national or agency-recognized emergency or disaster.

(e) A permit, license, certificate, or similar instrument issued as a means to regulate public health, safety, or the environment, unless the Office of National Drug Control Policy specifically designates it to be a covered transaction.

(f) An incidental benefit that results from ordinary governmental operations.

(g) Any other transaction if the application of an exclusion to the transaction is prohibited by law.

§ 1404.220 Are any procurement contracts included as covered transactions?

(a) Covered transactions under this part—

(1) Do not include any procurement contracts awarded directly by a Federal agency; but

(2) Do include some procurement contracts awarded by non-Federal participants in nonprocurement covered transactions (see appendix to this part).

(b) Specifically, a contract for goods or services is a covered transaction if any of the following applies:

(1) The contract is awarded by a participant in a nonprocurement transaction that is covered under § 1404.210, and the amount of the contract is expected to equal or exceed \$25,000.

(2) The contract requires the consent of a(n) Office of National Drug Control Policy official. In that case, the contract, regardless of the amount, always is a covered transaction, and it does not matter who awarded it. For example, it could be a subcontract awarded by a contractor at a tier below a nonprocurement transaction, as shown in the appendix to this part.

(3) The contract is for federally-required audit services.

§ 1404.225 How do I know if a transaction in which I may participate is a covered transaction?

As a participant in a transaction, you will know that it is a covered transaction because the agency regulations governing the transaction, the appropriate agency official, or participant at the next higher tier who enters into the transaction with you, will tell

21 CFR Ch. III (4–1–11 Edition)

you that you must comply with applicable portions of this part.

Subpart C—Responsibilities of Participants Regarding Transactions

DOING BUSINESS WITH OTHER PERSONS

§ 1404.300 What must I do before I enter into a covered transaction with another person at the next lower tier?

When you enter into a covered transaction with another person at the next lower tier, you must verify that the person with whom you intend to do business is not excluded or disqualified. You do this by:

(a) Checking the *EPLS*; or

(b) Collecting a certification from that person if allowed by this rule; or

(c) Adding a clause or condition to the covered transaction with that person.

§ 1404.305 May I enter into a covered transaction with an excluded or disqualified person?

(a) You as a participant may not enter into a covered transaction with an excluded person, unless the Office of National Drug Control Policy grants an exception under § 1404.120.

(b) You may not enter into any transaction with a person who is disqualified from that transaction, unless you have obtained an exception under the disqualifying statute, Executive order, or regulation.

§ 1404.310 What must I do if a Federal agency excludes a person with whom I am already doing business in a covered transaction?

(a) You as a participant may continue covered transactions with an excluded person if the transactions were in existence when the agency excluded the person. However, you are not required to continue the transactions, and you may consider termination. You should make a decision about whether to terminate and the type of termination action, if any, only after a thorough review to ensure that the action is proper and appropriate.

(b) You may not renew or extend covered transactions (other than no-cost time extensions) with any excluded

Office of National Drug Control Policy

§ 1404.340

person, unless the Office of National Drug Control Policy grants an exception under §1404.120.

§ 1404.315 May I use the services of an excluded person as a principal under a covered transaction?

(a) You as a participant may continue to use the services of an excluded person as a principal under a covered transaction if you were using the services of that person in the transaction before the person was excluded. However, you are not required to continue using that person's services as a principal. You should make a decision about whether to discontinue that person's services only after a thorough review to ensure that the action is proper and appropriate.

(b) You may not begin to use the services of an excluded person as a principal under a covered transaction unless the Office of National Drug Control Policy grants an exception under §1404.120.

§ 1404.320 Must I verify that principals of my covered transactions are eligible to participate?

Yes, you as a participant are responsible for determining whether any of your principals of your covered transactions is excluded or disqualified from participating in the transaction. You may decide the method and frequency by which you do so. You may, but you are not required to, check the *EPLS*.

§ 1404.325 What happens if I do business with an excluded person in a covered transaction?

If as a participant you knowingly do business with an excluded person, we may disallow costs, annul or terminate the transaction, issue a stop work order, debar or suspend you, or take other remedies as appropriate.

§ 1404.330 What requirements must I pass down to persons at lower tiers with whom I intend to do business?

Before entering into a covered transaction with a participant at the next lower tier, you must require that participant to—

(a) Comply with this subpart as a condition of participation in the transaction. You may do so using any meth-

od(s), unless §1404.440 requires you to use specific methods.

(b) Pass the requirement to comply with this subpart to each person with whom the participant enters into a covered transaction at the next lower tier.

DISCLOSING INFORMATION—PRIMARY TIER PARTICIPANTS

§ 1404.335 What information must I provide before entering into a covered transaction with the Office of National Drug Control Policy?

Before you enter into a covered transaction at the primary tier, you as the participant must notify the Office of National Drug Control Policy office that is entering into the transaction with you, if you know that you or any of the principals for that covered transaction:

(a) Are presently excluded or disqualified;

(b) Have been convicted within the preceding three years of any of the offenses listed in §1404.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;

(c) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in §1404.800(a); or

(d) Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

§ 1404.340 If I disclose unfavorable information required under § 1404.335, will I be prevented from participating in the transaction?

As a primary tier participant, your disclosure of unfavorable information about yourself or a principal under §1404.335 will not necessarily cause us to deny your participation in the covered transaction. We will consider the information when we determine whether to enter into the covered transaction. We also will consider any additional information or explanation that you elect to submit with the disclosed information.

§ 1404.345

§ 1404.345 What happens if I fail to disclose information required under § 1404.335?

If we later determine that you failed to disclose information under § 1404.335 that you knew at the time you entered into the covered transaction, we may—

(a) Terminate the transaction for material failure to comply with the terms and conditions of the transaction; or

(b) Pursue any other available remedies, including suspension and debarment.

§ 1404.350 What must I do if I learn of information required under § 1404.335 after entering into a covered transaction with the Office of National Drug Control Policy?

At any time after you enter into a covered transaction, you must give immediate written notice to the Office of National Drug Control Policy office with which you entered into the transaction if you learn either that—

(a) You failed to disclose information earlier, as required by § 1404.335; or

(b) Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in § 1404.335.

DISCLOSING INFORMATION—LOWER TIER PARTICIPANTS

§ 1404.355 What information must I provide to a higher tier participant before entering into a covered transaction with that participant?

Before you enter into a covered transaction with a person at the next higher tier, you as a lower tier participant must notify that person if you know that you or any of the principals are presently excluded or disqualified.

§ 1404.360 What happens if I fail to disclose the information required under § 1404.355?

If we later determine that you failed to tell the person at the higher tier that you were excluded or disqualified at the time you entered into the covered transaction with that person, we may pursue any available remedies, including suspension and debarment.

21 CFR Ch. III (4–1–11 Edition)

§ 1404.365 What must I do if I learn of information required under § 1404.355 after entering into a covered transaction with a higher tier participant?

At any time after you enter into a lower tier covered transaction with a person at a higher tier, you must provide immediate written notice to that person if you learn either that—

(a) You failed to disclose information earlier, as required by § 1404.355; or

(b) Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in § 1404.355.

Subpart D—Responsibilities of Office of National Drug Control Policy Officials Regarding Transactions

§ 1404.400 May I enter into a transaction with an excluded or disqualified person?

(a) You as an agency official may not enter into a covered transaction with an excluded person unless you obtain an exception under § 1404.120.

(b) You may not enter into any transaction with a person who is disqualified from that transaction, unless you obtain a waiver or exception under the statute, Executive order, or regulation that is the basis for the person's disqualification.

§ 1404.405 May I enter into a covered transaction with a participant if a principal of the transaction is excluded?

As an agency official, you may not enter into a covered transaction with a participant if you know that a principal of the transaction is excluded, unless you obtain an exception under § 1404.120.

§ 1404.410 May I approve a participant's use of the services of an excluded person?

After entering into a covered transaction with a participant, you as an agency official may not approve a participant's use of an excluded person as a principal under that transaction, unless you obtain an exception under § 1404.120.

§ 1404.415 What must I do if a Federal agency excludes the participant or a principal after I enter into a covered transaction?

(a) You as an agency official may continue covered transactions with an excluded person, or under which an excluded person is a principal, if the transactions were in existence when the person was excluded. You are not required to continue the transactions, however, and you may consider termination. You should make a decision about whether to terminate and the type of termination action, if any, only after a thorough review to ensure that the action is proper.

(b) You may not renew or extend covered transactions (other than no-cost time extensions) with any excluded person, or under which an excluded person is a principal, unless you obtain an exception under § 1404.120.

§ 1404.420 May I approve a transaction with an excluded or disqualified person at a lower tier?

If a transaction at a lower tier is subject to your approval, you as an agency official may not approve—

(a) A covered transaction with a person who is currently excluded, unless you obtain an exception under § 1404.120; or

(b) A transaction with a person who is disqualified from that transaction, unless you obtain a waiver or exception under the statute, Executive order, or regulation that is the basis for the person's disqualification.

§ 1404.425 When do I check to see if a person is excluded or disqualified?

As an agency official, you must check to see if a person is excluded or disqualified before you—

(a) Enter into a primary tier covered transaction;

(b) Approve a principal in a primary tier covered transaction;

(c) Approve a lower tier participant if agency approval of the lower tier participant is required; or

(d) Approve a principal in connection with a lower tier transaction if agency approval of the principal is required.

§ 1404.430 How do I check to see if a person is excluded or disqualified?

You check to see if a person is excluded or disqualified in two ways:

(a) You as an agency official must check the *EPLS* when you take any action listed in § 1404.425.

(b) You must review information that a participant gives you, as required by § 1404.335, about its status or the status of the principals of a transaction.

§ 1404.435 What must I require of a primary tier participant?

You as an agency official must require each participant in a primary tier covered transaction to—

(a) Comply with subpart C of this part as a condition of participation in the transaction; and

(b) Communicate the requirement to comply with Subpart C of this part to persons at the next lower tier with whom the primary tier participant enters into covered transactions.

§ 1404.440 What method do I use to communicate those requirements to participants?

You must obtain certifications from participants that they will comply with subpart C of this part and that they will obtain similar certifications from lower-tier participants.

[68 FR 66581, Nov. 26, 2003]

§ 1404.445 What action may I take if a primary tier participant knowingly does business with an excluded or disqualified person?

If a participant knowingly does business with an excluded or disqualified person, you as an agency official may refer the matter for suspension and debarment consideration. You may also disallow costs, annul or terminate the transaction, issue a stop work order, or take any other appropriate remedy.

§ 1404.450 What action may I take if a primary tier participant fails to disclose the information required under § 1404.335?

If you as an agency official determine that a participant failed to disclose information, as required by § 1404.335, at the time it entered into a covered transaction with you, you may—

§ 1404.455

(a) Terminate the transaction for material failure to comply with the terms and conditions of the transaction; or

(b) Pursue any other available remedies, including suspension and debarment.

§ 1404.455 What may I do if a lower tier participant fails to disclose the information required under § 1404.355 to the next higher tier?

If you as an agency official determine that a lower tier participant failed to disclose information, as required by § 1404.355, at the time it entered into a covered transaction with a participant at the next higher tier, you may pursue any remedies available to you, including the initiation of a suspension or debarment action.

Subpart E—Excluded Parties List System

§ 1404.500 What is the purpose of the Excluded Parties List System (EPLS)?

The *EPLS* is a widely available source of the most current information about persons who are excluded or disqualified from covered transactions.

§ 1404.505 Who uses the EPLS?

(a) Federal agency officials use the *EPLS* to determine whether to enter into a transaction with a person, as required under § 1404.430.

(b) Participants also may, but are not required to, use the *EPLS* to determine if—

(1) Principals of their transactions are excluded or disqualified, as required under § 1404.320; or

(2) Persons with whom they are entering into covered transactions at the next lower tier are excluded or disqualified.

(c) The *EPLS* is available to the general public.

§ 1404.510 Who maintains the EPLS?

In accordance with the OMB guidelines, the General Services Administration (GSA) maintains the *EPLS*. When a Federal agency takes an action to exclude a person under the nonprocurement or procurement debarment and suspension system, the agency enters

21 CFR Ch. III (4–1–11 Edition)

the information about the excluded person into the *EPLS*.

§ 1404.515 What specific information is in the EPLS?

(a) At a minimum, the *EPLS* indicates—

(1) The full name (where available) and address of each excluded or disqualified person, in alphabetical order, with cross references if more than one name is involved in a single action;

(2) The type of action;

(3) The cause for the action;

(4) The scope of the action;

(5) Any termination date for the action;

(6) The agency and name and telephone number of the agency point of contact for the action; and

(7) The Dun and Bradstreet Number (DUNS), or other similar code approved by the GSA, of the excluded or disqualified person, if available.

(b)(1) The database for the *EPLS* includes a field for the Taxpayer Identification Number (TIN) (the social security number (SSN) for an individual) of an excluded or disqualified person.

(2) Agencies disclose the SSN of an individual to verify the identity of an individual, only if permitted under the Privacy Act of 1974 and, if appropriate, the Computer Matching and Privacy Protection Act of 1988, as codified in 5 U.S.C. 552(a).

§ 1404.520 Who places the information into the EPLS?

Federal officials who take actions to exclude persons under this part or officials who are responsible for identifying disqualified persons must enter the following information about those persons into the *EPLS*:

(a) Information required by § 1404.515(a);

(b) The Taxpayer Identification Number (TIN) of the excluded or disqualified person, including the social security number (SSN) for an individual, if the number is available and may be disclosed under law;

(c) Information about an excluded or disqualified person, generally within five working days, after—

(1) Taking an exclusion action;

(2) Modifying or rescinding an exclusion action;

Office of National Drug Control Policy

§ 1404.615

(3) Finding that a person is disqualified; or

(4) Finding that there has been a change in the status of a person who is listed as disqualified.

§ 1404.525 Whom do I ask if I have questions about a person in the EPLS?

If you have questions about a person in the *EPLS*, ask the point of contact for the Federal agency that placed the person's name into the *EPLS*. You may find the agency point of contact from the *EPLS*.

§ 1404.530 Where can I find the EPLS?

(a) You may access the *EPLS* through the Internet, currently at <http://epls.arnet.gov>.

(b) As of November 26, 2003, you may also subscribe to a printed version. However, we anticipate discontinuing the printed version. Until it is discontinued, you may obtain the printed version by purchasing a yearly sub-

scription from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or by calling the Government Printing Office Inquiry and Order Desk at (202) 783-3238.

Subpart F—General Principles Relating to Suspension and Debarment Actions

§ 1404.600 How do suspension and debarment actions start?

When we receive information from any source concerning a cause for suspension or debarment, we will promptly report and investigate it. We refer the question of whether to suspend or debar you to our suspending or debarring official for consideration, if appropriate.

§ 1404.605 How does suspension differ from debarment?

Suspension differs from debarment in that—

A suspending official . . .	A debarring official . . .
(a) Imposes suspension as a temporary status of ineligibility for procurement and nonprocurement transactions, pending completion of an investigation or legal proceedings.	Imposes debarment for a specified period as a final determination that a person is not presently responsible.
(b) Must—	Must conclude, based on a <i>preponderance of the evidence</i> , that the person has engaged in conduct that warrants debarment.
(1) Have <i>adequate evidence</i> that there may be a cause for debarment of a person; and.	
(2) Conclude that <i>immediate action</i> is necessary to protect the Federal interest.	
(c) Usually imposes the suspension <i>first</i> , and then promptly notifies the suspended person, giving the person an opportunity to contest the suspension and have it lifted.	Imposes debarment <i>after</i> giving the respondent notice of the action and an opportunity to contest the proposed debarment.

§ 1404.610 What procedures does the Office of National Drug Control Policy use in suspension and debarment actions?

In deciding whether to suspend or debar you, we handle the actions as informally as practicable, consistent with principles of fundamental fairness.

(a) For suspension actions, we use the procedures in this subpart and subpart G of this part.

(b) For debarment actions, we use the procedures in this subpart and subpart H of this part.

§ 1404.615 How does the Office of National Drug Control Policy notify a person of a suspension or debarment action?

(a) The suspending or debarring official sends a written notice to the last known street address, facsimile number, or e-mail address of—

(1) You or your identified counsel; or

(2) Your agent for service of process, or any of your partners, officers, directors, owners, or joint venturers.

(b) The notice is effective if sent to any of these persons.

§ 1404.620 Do Federal agencies coordinate suspension and debarment actions?

Yes, when more than one Federal agency has an interest in a suspension or debarment, the agencies may consider designating one agency as the lead agency for making the decision. Agencies are encouraged to establish methods and procedures for coordinating their suspension and debarment actions.

§ 1404.625 What is the scope of a suspension or debarment?

If you are suspended or debarred, the suspension or debarment is effective as follows:

(a) Your suspension or debarment constitutes suspension or debarment of all of your divisions and other organizational elements from all covered transactions, unless the suspension or debarment decision is limited—

(1) By its terms to one or more specifically identified individuals, divisions, or other organizational elements; or

(2) To specific types of transactions.

(b) Any affiliate of a participant may be included in a suspension or debarment action if the suspending or debarring official—

(1) Officially names the affiliate in the notice; and

(2) Gives the affiliate an opportunity to contest the action.

§ 1404.630 May the Office of National Drug Control Policy impute conduct of one person to another?

For purposes of actions taken under this rule, we may impute conduct as follows:

(a) *Conduct imputed from an individual to an organization.* We may impute the fraudulent, criminal, or other improper conduct of any officer, director, shareholder, partner, employee, or other individual associated with an organization, to that organization when the improper conduct occurred in connection with the individual's performance of duties for or on behalf of that organization, or with the organization's knowledge, approval or acquiescence. The organization's acceptance of the benefits derived from the conduct is evidence of knowledge, approval or acquiescence.

(b) *Conduct imputed from an organization to an individual, or between individuals.* We may impute the fraudulent, criminal, or other improper conduct of any organization to an individual, or from one individual to another individual, if the individual to whom the improper conduct is imputed either participated in, had knowledge of, or reason to know of the improper conduct.

(c) *Conduct imputed from one organization to another organization.* We may impute the fraudulent, criminal, or other improper conduct of one organization to another organization when the improper conduct occurred in connection with a partnership, joint venture, joint application, association or similar arrangement, or when the organization to whom the improper conduct is imputed has the power to direct, manage, control or influence the activities of the organization responsible for the improper conduct. Acceptance of the benefits derived from the conduct is evidence of knowledge, approval or acquiescence.

§ 1404.635 May the Office of National Drug Control Policy settle a debarment or suspension action?

Yes, we may settle a debarment or suspension action at any time if it is in the best interest of the Federal Government.

§ 1404.640 May a settlement include a voluntary exclusion?

Yes, if we enter into a settlement with you in which you agree to be excluded, it is called a voluntary exclusion and has governmentwide effect.

§ 1404.645 Do other Federal agencies know if the Office of National Drug Control Policy agrees to a voluntary exclusion?

(a) Yes, we enter information regarding a voluntary exclusion into the *EPLS*.

(b) Also, any agency or person may contact us to find out the details of a voluntary exclusion.

Subpart G—Suspension**§ 1404.700 When may the suspending official issue a suspension?**

Suspension is a serious action. Using the procedures of this subpart and subpart F of this part, the suspending official may impose suspension only when that official determines that—

- (a) There exists an indictment for, or other adequate evidence to suspect, an offense listed under § 1404.800(a), or
- (b) There exists adequate evidence to suspect any other cause for debarment listed under § 1404.800(b) through (d); and
- (c) Immediate action is necessary to protect the public interest.

§ 1404.705 What does the suspending official consider in issuing a suspension?

(a) In determining the adequacy of the evidence to support the suspension, the suspending official considers how much information is available, how credible it is given the circumstances, whether or not important allegations are corroborated, and what inferences can reasonably be drawn as a result. During this assessment, the suspending official may examine the basic documents, including grants, cooperative agreements, loan authorizations, contracts, and other relevant documents.

(b) An indictment, conviction, civil judgment, or other official findings by Federal, State, or local bodies that determine factual and/or legal matters, constitutes adequate evidence for purposes of suspension actions.

(c) In deciding whether immediate action is needed to protect the public interest, the suspending official has wide discretion. For example, the suspending official may infer the necessity for immediate action to protect the public interest either from the nature of the circumstances giving rise to a cause for suspension or from potential business relationships or involvement with a program of the Federal Government.

§ 1404.710 When does a suspension take effect?

A suspension is effective when the suspending official signs the decision to suspend.

§ 1404.715 What notice does the suspending official give me if I am suspended?

After deciding to suspend you, the suspending official promptly sends you a Notice of Suspension advising you—

- (a) That you have been suspended;
- (b) That your suspension is based on—
 - (1) An indictment;
 - (2) A conviction;
 - (3) Other adequate evidence that you have committed irregularities which seriously reflect on the propriety of further Federal Government dealings with you; or
 - (4) Conduct of another person that has been imputed to you, or your affiliation with a suspended or debarred person;
- (c) Of any other irregularities in terms sufficient to put you on notice without disclosing the Federal Government's evidence;
- (d) Of the cause(s) upon which we relied under § 1404.700 for imposing suspension;
- (e) That your suspension is for a temporary period pending the completion of an investigation or resulting legal or debarment proceedings;
- (f) Of the applicable provisions of this subpart, Subpart F of this part, and any other Office of National Drug Control Policy procedures governing suspension decision making; and
- (g) Of the governmentwide effect of your suspension from procurement and nonprocurement programs and activities.

§ 1404.720 How may I contest a suspension?

If you as a respondent wish to contest a suspension, you or your representative must provide the suspending official with information in opposition to the suspension. You may do this orally or in writing, but any information provided orally that you consider important must also be submitted in writing for the official record.

§ 1404.725 How much time do I have to contest a suspension?

(a) As a respondent you or your representative must either send, or make arrangements to appear and present,

§ 1404.730

21 CFR Ch. III (4–1–11 Edition)

the information and argument to the suspending official within 30 days after you receive the Notice of Suspension.

(b) We consider the notice to be received by you—

(1) When delivered, if we mail the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if we send the notice by facsimile or five days after we send it if the facsimile is undeliverable; or

(3) When delivered, if we send the notice by e-mail or five days after we send it if the e-mail is undeliverable.

§ 1404.730 What information must I provide to the suspending official if I contest a suspension?

(a) In addition to any information and argument in opposition, as a respondent your submission to the suspending official must identify—

(1) Specific facts that contradict the statements contained in the Notice of Suspension. A general denial is insufficient to raise a genuine dispute over facts material to the suspension;

(2) All existing, proposed, or prior exclusions under regulations implementing E.O. 12549 and all similar actions taken by Federal, state, or local agencies, including administrative agreements that affect only those agencies;

(3) All criminal and civil proceedings not included in the Notice of Suspension that grew out of facts relevant to the cause(s) stated in the notice; and

(4) All of your affiliates.

(b) If you fail to disclose this information, or provide false information, the Office of National Drug Control Policy may seek further criminal, civil or administrative action against you, as appropriate.

§ 1404.735 Under what conditions do I get an additional opportunity to challenge the facts on which the suspension is based?

(a) You as a respondent will not have an additional opportunity to challenge the facts if the suspending official determines that—

(1) Your suspension is based upon an indictment, conviction, civil judgment, or other finding by a Federal, State, or local body for which an opportunity to contest the facts was provided;

(2) Your presentation in opposition contains only general denials to information contained in the Notice of Suspension;

(3) The issues raised in your presentation in opposition to the suspension are not factual in nature, or are not material to the suspending official's initial decision to suspend, or the official's decision whether to continue the suspension; or

(4) On the basis of advice from the Department of Justice, an office of the United States Attorney, a State attorney general's office, or a State or local prosecutor's office, that substantial interests of the government in pending or contemplated legal proceedings based on the same facts as the suspension would be prejudiced by conducting fact-finding.

(b) You will have an opportunity to challenge the facts if the suspending official determines that—

(1) The conditions in paragraph (a) of this section do not exist; and

(2) Your presentation in opposition raises a genuine dispute over facts material to the suspension.

(c) If you have an opportunity to challenge disputed material facts under this section, the suspending official or designee must conduct additional proceedings to resolve those facts.

§ 1404.740 Are suspension proceedings formal?

(a) Suspension proceedings are conducted in a fair and informal manner. The suspending official may use flexible procedures to allow you to present matters in opposition. In so doing, the suspending official is not required to follow formal rules of evidence or procedure in creating an official record upon which the official will base a final suspension decision.

(b) You as a respondent or your representative must submit any documentary evidence you want the suspending official to consider.

§ 1404.745 How is fact-finding conducted?

(a) If fact-finding is conducted—

(1) You may present witnesses and other evidence, and confront any witness presented; and

Office of National Drug Control Policy

§ 1404.800

(2) The fact-finder must prepare written findings of fact for the record.

(b) A transcribed record of fact-finding proceedings must be made, unless you as a respondent and the Office of National Drug Control Policy agree to waive it in advance. If you want a copy of the transcribed record, you may purchase it.

§ 1404.750 What does the suspending official consider in deciding whether to continue or terminate my suspension?

(a) The suspending official bases the decision on all information contained in the official record. The record includes—

(1) All information in support of the suspending official's initial decision to suspend you;

(2) Any further information and argument presented in support of, or opposition to, the suspension; and

(3) Any transcribed record of fact-finding proceedings.

(b) The suspending official may refer disputed material facts to another official for findings of fact. The suspending official may reject any resulting findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.

§ 1404.755 When will I know whether the suspension is continued or terminated?

The suspending official must make a written decision whether to continue, modify, or terminate your suspension within 45 days of closing the official record. The official record closes upon the suspending official's receipt of final submissions, information and findings of fact, if any. The suspending official may extend that period for good cause.

§ 1404.760 How long may my suspension last?

(a) If legal or debarment proceedings are initiated at the time of, or during your suspension, the suspension may continue until the conclusion of those proceedings. However, if proceedings are not initiated, a suspension may not exceed 12 months.

(b) The suspending official may extend the 12 month limit under paragraph (a) of this section for an addi-

tional 6 months if an office of a U.S. Assistant Attorney General, U.S. Attorney, or other responsible prosecuting official requests an extension in writing. In no event may a suspension exceed 18 months without initiating proceedings under paragraph (a) of this section.

(c) The suspending official must notify the appropriate officials under paragraph (b) of this section of an impending termination of a suspension at least 30 days before the 12 month period expires to allow the officials an opportunity to request an extension.

Subpart H—Debarment

§ 1404.800 What are the causes for debarment?

We may debar a person for—

(a) Conviction of or civil judgment for—

(1) Commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public or private agreement or transaction;

(2) Violation of Federal or State anti-trust statutes, including those proscribing price fixing between competitors, allocation of customers between competitors, and bid rigging;

(3) Commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; or

(4) Commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;

(b) Violation of the terms of a public agreement or transaction so serious as to affect the integrity of an agency program, such as—

(1) A willful failure to perform in accordance with the terms of one or more public agreements or transactions;

(2) A history of failure to perform or of unsatisfactory performance of one or more public agreements or transactions; or

(3) A willful violation of a statutory or regulatory provision or requirement applicable to a public agreement or transaction;

§ 1404.805

21 CFR Ch. III (4–1–11 Edition)

(c) Any of the following causes:

(1) A nonprocurement debarment by any Federal agency taken before October 1, 1988, or a procurement debarment by any Federal agency taken pursuant to 48 CFR part 9, subpart 9.4, before August 25, 1995;

(2) Knowingly doing business with an ineligible person, except as permitted under § 1404.120;

(3) Failure to pay a single substantial debt, or a number of outstanding debts (including disallowed costs and overpayments, but not including sums owed the Federal Government under the Internal Revenue Code) owed to any Federal agency or instrumentality, provided the debt is uncontested by the debtor or, if contested, provided that the debtor's legal and administrative remedies have been exhausted;

(4) Violation of a material provision of a voluntary exclusion agreement entered into under § 1404.640 or of any settlement of a debarment or suspension action; or

(5) Violation of the provisions of the Drug-Free Workplace Act of 1988 (41 U.S.C. 701); or

(d) Any other cause of so serious or compelling a nature that it affects your present responsibility.

§ 1404.805 What notice does the debarring official give me if I am proposed for debarment?

After consideration of the causes in § 1404.800 of this subpart, if the debarring official proposes to debar you, the official sends you a Notice of Proposed Debarment, pursuant to § 1404.615, advising you—

(a) That the debarring official is considering debarring you;

(b) Of the reasons for proposing to debar you in terms sufficient to put you on notice of the conduct or transactions upon which the proposed debarment is based;

(c) Of the cause(s) under § 1404.800 upon which the debarring official relied for proposing your debarment;

(d) Of the applicable provisions of this subpart, Subpart F of this part, and any other Office of National Drug Control Policy procedures governing debarment; and

(e) Of the governmentwide effect of a debarment from procurement and non-procurement programs and activities.

§ 1404.810 When does a debarment take effect?

A debarment is not effective until the debarring official issues a decision. The debarring official does not issue a decision until the respondent has had an opportunity to contest the proposed debarment.

§ 1404.815 How may I contest a proposed debarment?

If you as a respondent wish to contest a proposed debarment, you or your representative must provide the debarring official with information in opposition to the proposed debarment. You may do this orally or in writing, but any information provided orally that you consider important must also be submitted in writing for the official record.

§ 1404.820 How much time do I have to contest a proposed debarment?

(a) As a respondent you or your representative must either send, or make arrangements to appear and present, the information and argument to the debarring official within 30 days after you receive the Notice of Proposed Debarment.

(b) We consider the Notice of Proposed Debarment to be received by you—

(1) When delivered, if we mail the notice to the last known street address, or five days after we send it if the letter is undeliverable;

(2) When sent, if we send the notice by facsimile or five days after we send it if the facsimile is undeliverable; or

(3) When delivered, if we send the notice by e-mail or five days after we send it if the e-mail is undeliverable.

§ 1404.825 What information must I provide to the debarring official if I contest a proposed debarment?

(a) In addition to any information and argument in opposition, as a respondent your submission to the debarring official must identify—

(1) Specific facts that contradict the statements contained in the Notice of

Office of National Drug Control Policy

§ 1404.845

Proposed Debarment. Include any information about any of the factors listed in §1404.860. A general denial is insufficient to raise a genuine dispute over facts material to the debarment;

(2) All existing, proposed, or prior exclusions under regulations implementing E.O. 12549 and all similar actions taken by Federal, State, or local agencies, including administrative agreements that affect only those agencies;

(3) All criminal and civil proceedings not included in the Notice of Proposed Debarment that grew out of facts relevant to the cause(s) stated in the notice; and

(4) All of your affiliates.

(b) If you fail to disclose this information, or provide false information, the Office of National Drug Control Policy may seek further criminal, civil or administrative action against you, as appropriate.

§ 1404.830 Under what conditions do I get an additional opportunity to challenge the facts on which a proposed debarment is based?

(a) You as a respondent will not have an additional opportunity to challenge the facts if the debarring official determines that—

(1) Your debarment is based upon a conviction or civil judgment;

(2) Your presentation in opposition contains only general denials to information contained in the Notice of Proposed Debarment; or

(3) The issues raised in your presentation in opposition to the proposed debarment are not factual in nature, or are not material to the debarring official's decision whether to debar.

(b) You will have an additional opportunity to challenge the facts if the debarring official determines that—

(1) The conditions in paragraph (a) of this section do not exist; and

(2) Your presentation in opposition raises a genuine dispute over facts material to the proposed debarment.

(c) If you have an opportunity to challenge disputed material facts under this section, the debarring official or designee must conduct additional proceedings to resolve those facts.

§ 1404.835 Are debarment proceedings formal?

(a) Debarment proceedings are conducted in a fair and informal manner. The debarring official may use flexible procedures to allow you as a respondent to present matters in opposition. In so doing, the debarring official is not required to follow formal rules of evidence or procedure in creating an official record upon which the official will base the decision whether to debar.

(b) You or your representative must submit any documentary evidence you want the debarring official to consider.

§ 1404.840 How is fact-finding conducted?

(a) If fact-finding is conducted—

(1) You may present witnesses and other evidence, and confront any witness presented; and

(2) The fact-finder must prepare written findings of fact for the record.

(b) A transcribed record of fact-finding proceedings must be made, unless you as a respondent and the Office of National Drug Control Policy agree to waive it in advance. If you want a copy of the transcribed record, you may purchase it.

§ 1404.845 What does the debarring official consider in deciding whether to debar me?

(a) The debarring official may debar you for any of the causes in §1404.800. However, the official need not debar you even if a cause for debarment exists. The official may consider the seriousness of your acts or omissions and the mitigating or aggravating factors set forth at §1404.860.

(b) The debarring official bases the decision on all information contained in the official record. The record includes—

(1) All information in support of the debarring official's proposed debarment;

(2) Any further information and argument presented in support of, or in opposition to, the proposed debarment; and

(3) Any transcribed record of fact-finding proceedings.

(c) The debarring official may refer disputed material facts to another official for findings of fact. The debarring

§ 1404.850

21 CFR Ch. III (4–1–11 Edition)

official may reject any resultant findings, in whole or in part, only after specifically determining them to be arbitrary, capricious, or clearly erroneous.

§ 1404.850 What is the standard of proof in a debarment action?

(a) In any debarment action, we must establish the cause for debarment by a preponderance of the evidence.

(b) If the proposed debarment is based upon a conviction or civil judgment, the standard of proof is met.

§ 1404.855 Who has the burden of proof in a debarment action?

(a) We have the burden to prove that a cause for debarment exists.

(b) Once a cause for debarment is established, you as a respondent have the burden of demonstrating to the satisfaction of the debarring official that you are presently responsible and that debarment is not necessary.

§ 1404.860 What factors may influence the debarring official's decision?

This section lists the mitigating and aggravating factors that the debarring official may consider in determining whether to debar you and the length of your debarment period. The debarring official may consider other factors if appropriate in light of the circumstances of a particular case. The existence or nonexistence of any factor, such as one of those set forth in this section, is not necessarily determinative of your present responsibility. In making a debarment decision, the debarring official may consider the following factors:

(a) The actual or potential harm or impact that results or may result from the wrongdoing.

(b) The frequency of incidents and/or duration of the wrongdoing.

(c) Whether there is a pattern or prior history of wrongdoing. For example, if you have been found by another Federal agency or a State agency to have engaged in wrongdoing similar to that found in the debarment action, the existence of this fact may be used by the debarring official in determining that you have a pattern or prior history of wrongdoing.

(d) Whether you are or have been excluded or disqualified by an agency of the Federal Government or have not been allowed to participate in State or local contracts or assistance agreements on a basis of conduct similar to one or more of the causes for debarment specified in this part.

(e) Whether you have entered into an administrative agreement with a Federal agency or a State or local government that is not governmentwide but is based on conduct similar to one or more of the causes for debarment specified in this part.

(f) Whether and to what extent you planned, initiated, or carried out the wrongdoing.

(g) Whether you have accepted responsibility for the wrongdoing and recognize the seriousness of the misconduct that led to the cause for debarment.

(h) Whether you have paid or agreed to pay all criminal, civil and administrative liabilities for the improper activity, including any investigative or administrative costs incurred by the government, and have made or agreed to make full restitution.

(i) Whether you have cooperated fully with the government agencies during the investigation and any court or administrative action. In determining the extent of cooperation, the debarring official may consider when the cooperation began and whether you disclosed all pertinent information known to you.

(j) Whether the wrongdoing was pervasive within your organization.

(k) The kind of positions held by the individuals involved in the wrongdoing.

(l) Whether your organization took appropriate corrective action or remedial measures, such as establishing ethics training and implementing programs to prevent recurrence.

(m) Whether your principals tolerated the offense.

(n) Whether you brought the activity cited as a basis for the debarment to the attention of the appropriate government agency in a timely manner.

(o) Whether you have fully investigated the circumstances surrounding the cause for debarment and, if so, made the result of the investigation available to the debarring official.

Office of National Drug Control Policy

§ 1404.885

(p) Whether you had effective standards of conduct and internal control systems in place at the time the questioned conduct occurred.

(q) Whether you have taken appropriate disciplinary action against the individuals responsible for the activity which constitutes the cause for debarment.

(r) Whether you have had adequate time to eliminate the circumstances within your organization that led to the cause for the debarment.

(s) Other factors that are appropriate to the circumstances of a particular case.

§ 1404.865 How long may my debarment last?

(a) If the debarring official decides to debar you, your period of debarment will be based on the seriousness of the cause(s) upon which your debarment is based. Generally, debarment should not exceed three years. However, if circumstances warrant, the debarring official may impose a longer period of debarment.

(b) In determining the period of debarment, the debarring official may consider the factors in § 1404.860. If a suspension has preceded your debarment, the debarring official must consider the time you were suspended.

(c) If the debarment is for a violation of the provisions of the Drug-Free Workplace Act of 1988, your period of debarment may not exceed five years.

§ 1404.870 When do I know if the debarring official debars me?

(a) The debarring official must make a written decision whether to debar within 45 days of closing the official record. The official record closes upon the debarring official's receipt of final submissions, information and findings of fact, if any. The debarring official may extend that period for good cause.

(b) The debarring official sends you written notice, pursuant to § 1404.615 that the official decided, either—

(1) Not to debar you; or

(2) To debar you. In this event, the notice:

(i) Refers to the Notice of Proposed Debarment;

(ii) Specifies the reasons for your debarment;

(iii) States the period of your debarment, including the effective dates; and

(iv) Advises you that your debarment is effective for covered transactions and contracts that are subject to the Federal Acquisition Regulation (48 CFR chapter 1), throughout the executive branch of the Federal Government unless an agency head or an authorized designee grants an exception.

§ 1404.875 May I ask the debarring official to reconsider a decision to debar me?

Yes, as a debarred person you may ask the debarring official to reconsider the debarment decision or to reduce the time period or scope of the debarment. However, you must put your request in writing and support it with documentation.

§ 1404.880 What factors may influence the debarring official during reconsideration?

The debarring official may reduce or terminate your debarment based on—

(a) Newly discovered material evidence;

(b) A reversal of the conviction or civil judgment upon which your debarment was based;

(c) A bona fide change in ownership or management;

(d) Elimination of other causes for which the debarment was imposed; or

(e) Other reasons the debarring official finds appropriate.

§ 1404.885 May the debarring official extend a debarment?

(a) Yes, the debarring official may extend a debarment for an additional period, if that official determines that an extension is necessary to protect the public interest.

(b) However, the debarring official may not extend a debarment solely on the basis of the facts and circumstances upon which the initial debarment action was based.

(c) If the debarring official decides that a debarment for an additional period is necessary, the debarring official must follow the applicable procedures in this subpart, and subpart F of this part, to extend the debarment.

Subpart I—Definitions

§ 1404.900 Adequate evidence.

Adequate evidence means information sufficient to support the reasonable belief that a particular act or omission has occurred.

§ 1404.905 Affiliate.

Persons are *affiliates* of each other if, directly or indirectly, either one controls or has the power to control the other or a third person controls or has the power to control both. The ways we use to determine control include, but are not limited to—

- (a) Interlocking management or ownership;
- (b) Identity of interests among family members;
- (c) Shared facilities and equipment;
- (d) Common use of employees; or
- (e) A business entity which has been organized following the exclusion of a person which has the same or similar management, ownership, or principal employees as the excluded person.

§ 1404.910 Agency.

Agency means any United States executive department, military department, defense agency, or any other agency of the executive branch. Other agencies of the Federal government are not considered “agencies” for the purposes of this part unless they issue regulations adopting the governmentwide Debarment and Suspension system under Executive orders 12549 and 12689.

§ 1404.915 Agent or representative.

Agent or representative means any person who acts on behalf of, or who is authorized to commit, a participant in a covered transaction.

§ 1404.920 Civil judgment.

Civil judgment means the disposition of a civil action by any court of competent jurisdiction, whether by verdict, decision, settlement, stipulation, other disposition which creates a civil liability for the complained of wrongful acts, or a final determination of liability under the Program Fraud Civil Remedies Act of 1988 (31 U.S.C. 3801–3812).

§ 1404.925 Conviction.

Conviction means—

- (a) A judgment or any other determination of guilt of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or plea, including a plea of *nolo contendere*; or
- (b) Any other resolution that is the functional equivalent of a judgment, including probation before judgment and deferred prosecution. A disposition without the participation of the court is the functional equivalent of a judgment only if it includes an admission of guilt.

§ 1404.930 Debarment.

Debarment means an action taken by a debarring official under subpart H of this part to exclude a person from participating in covered transactions and transactions covered under the Federal Acquisition Regulation (48 CFR chapter 1). A person so excluded is debarred.

§ 1404.935 Debarring official.

(a) *Debarring official* means an agency official who is authorized to impose debarment. A debarring official is either—

- (1) The agency head; or
 - (2) An official designated by the agency head.
- (b) [Reserved]

§ 1404.940 Disqualified.

Disqualified means that a person is prohibited from participating in specified Federal procurement or non-procurement transactions as required under a statute, Executive order (other than Executive Orders 12549 and 12689) or other authority. Examples of disqualifications include persons prohibited under—

- (a) The Davis-Bacon Act (40 U.S.C. 276(a));
- (b) The equal employment opportunity acts and Executive orders; or
- (c) The Clean Air Act (42 U.S.C. 7606), Clean Water Act (33 U.S.C. 1368) and Executive Order 11738 (3 CFR, 1973 Comp., p. 799).

§ 1404.945 Excluded or exclusion.

Excluded or exclusion means—

- (a) That a person or commodity is prohibited from being a participant in

Office of National Drug Control Policy

§ 1404.1000

covered transactions, whether the person has been suspended; debarred; proposed for debarment under 48 CFR part 9, subpart 9.4; voluntarily excluded; or

(b) The act of excluding a person.

§ 1404.950 Excluded Parties List System

Excluded Parties List System (EPLS) means the list maintained and disseminated by the General Services Administration (GSA) containing the names and other information about persons who are ineligible. The *EPLS* system includes the printed version entitled, “List of Parties Excluded or Disqualified from Federal Procurement and Nonprocurement Programs,” so long as published.

§ 1404.955 Indictment.

Indictment means an indictment for a criminal offense. A presentment, information, or other filing by a competent authority charging a criminal offense shall be given the same effect as an indictment.

§ 1404.960 Ineligible or ineligibility.

Ineligible or ineligibility means that a person or commodity is prohibited from covered transactions because of an exclusion or disqualification.

§ 1404.965 Legal proceedings.

Legal proceedings means any criminal proceeding or any civil judicial proceeding, including a proceeding under the Program Fraud Civil Remedies Act (31 U.S.C. 3801–3812), to which the Federal Government or a State or local government or quasi-governmental authority is a party. The term also includes appeals from those proceedings.

§ 1404.970 Nonprocurement transaction.

(a) *Nonprocurement transaction* means any transaction, regardless of type (except procurement contracts), including, but not limited to the following:

- (1) Grants.
- (2) Cooperative agreements.
- (3) Scholarships.
- (4) Fellowships.
- (5) Contracts of assistance.
- (6) Loans.
- (7) Loan guarantees.
- (8) Subsidies.

(9) Insurances.

(10) Payments for specified uses.

(11) Donation agreements.

(b) A nonprocurement transaction at any tier does not require the transfer of Federal funds.

§ 1404.975 Notice.

Notice means a written communication served in person, sent by certified mail or its equivalent, or sent electronically by e-mail or facsimile. (See § 1404.615.)

§ 1404.980 Participant.

Participant means any person who submits a proposal for or who enters into a covered transaction, including an agent or representative of a participant.

§ 1404.985 Person.

Person means any individual, corporation, partnership, association, unit of government, or legal entity, however organized.

§ 1404.990 Preponderance of the evidence.

Preponderance of the evidence means proof by information that, compared with information opposing it, leads to the conclusion that the fact at issue is more probably true than not.

§ 1404.995 Principal.

Principal means—

(a) An officer, director, owner, partner, principal investigator, or other person within a participant with management or supervisory responsibilities related to a covered transaction; or

(b) A consultant or other person, whether or not employed by the participant or paid with Federal funds, who—

(1) Is in a position to handle Federal funds;

(2) Is in a position to influence or control the use of those funds; or,

(3) Occupies a technical or professional position capable of substantially influencing the development or outcome of an activity required to perform the covered transaction.

§ 1404.1000 Respondent.

Respondent means a person against whom an agency has initiated a debarment or suspension action.

§ 1404.1005

21 CFR Ch. III (4–1–11 Edition)

§ 1404.1005 State.

- (a) *State* means—
- (1) Any of the states of the United States;
 - (2) The District of Columbia;
 - (3) The Commonwealth of Puerto Rico;
 - (4) Any territory or possession of the United States; or
 - (5) Any agency or instrumentality of a state.
- (b) For purposes of this part, *State* does not include institutions of higher education, hospitals, or units of local government.

§ 1404.1010 Suspending official.

- (a) *Suspending official* means an agency official who is authorized to impose suspension. The suspending official is either:
- (1) The agency head; or
 - (2) An official designated by the agency head.
- (b) [Reserved]

§ 1404.1015 Suspension.

Suspension is an action taken by a suspending official under subpart G of this part that immediately prohibits a person from participating in covered transactions and transactions covered under the Federal Acquisition Regulation (48 CFR chapter 1) for a temporary period, pending completion of an agency investigation and any judicial or administrative proceedings that may ensue. A person so excluded is suspended.

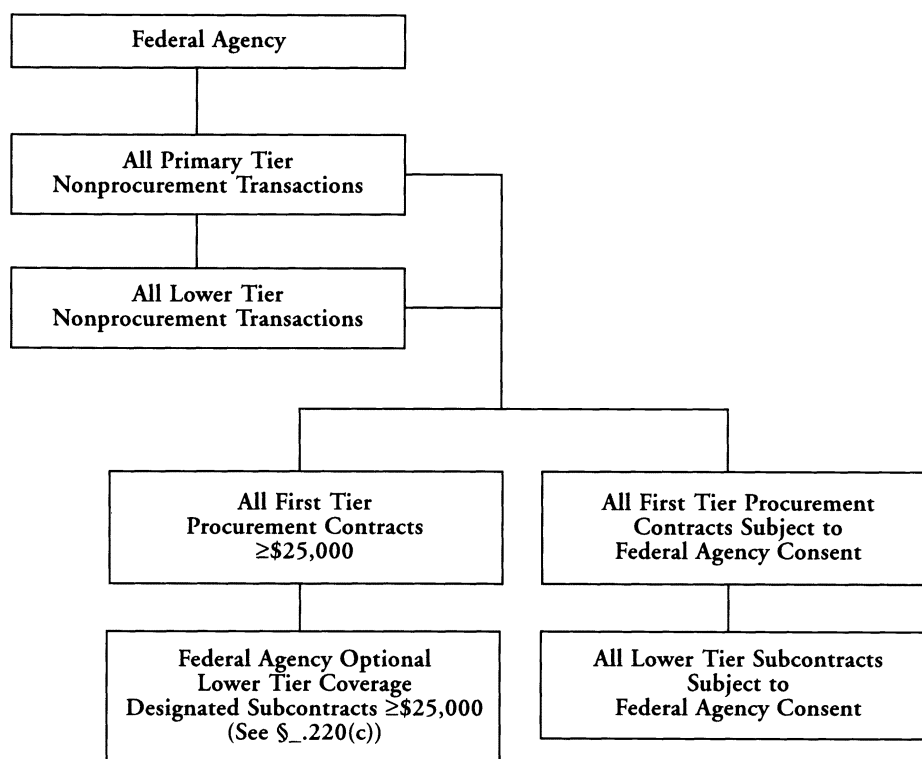
§ 1404.1020 Voluntary exclusion or voluntarily excluded.

- (a) *Voluntary exclusion* means a person's agreement to be excluded under the terms of a settlement between the person and one or more agencies. Voluntary exclusion must have governmentwide effect.
- (b) *Voluntarily excluded* means the status of a person who has agreed to a voluntary exclusion.

Subpart J [Reserved]

APPENDIX TO PART 1404—COVERED TRANSACTIONS

COVERED TRANSACTIONS

**PART 1405—GOVERNMENTWIDE REQUIREMENTS FOR DRUG-FREE WORKPLACE (FINANCIAL ASSISTANCE)****Subpart A—Purpose and Coverage**

Sec.

1405.100 What does this part do?

1405.105 Does this part apply to me?

1405.110 Are any of my Federal assistance awards exempt from this part?

1405.115 Does this part affect the Federal contracts that I receive?

Subpart B—Requirements for Recipients Other Than Individuals

1405.200 What must I do to comply with this part?

1405.205 What must I include in my drug-free workplace statement?

1405.210 To whom must I distribute my drug-free workplace statement?

1405.215 What must I include in my drug-free awareness program?

1405.220 By when must I publish my drug-free workplace statement and establish my drug-free awareness program?

1405.225 What actions must I take concerning employees who are convicted of drug violations in the workplace?

1405.230 How and when must I identify workplaces?

Subpart C—Requirements for Recipients Who Are Individuals

1405.300 What must I do to comply with this part if I am an individual recipient?